

Will Trump use FDA's new CGMP and FSVP Rules to Control Food Imports?

According to the website Gizmodo, a December, 2016 conversation between now-Commerce Secretary Wilbur Ross and then-President-elect Trump discussed using food safety inspections as a trade barrier. According to the recording, Trump and Ross discuss "playing the same game" as Japan, which closely inspects and bars unsanitary food from entry. Of course, new *sub silentio* food enforcement policies by the FDA would impose additional burdens on food producers and importers, who are already working on FDA's major new regulations on food safety and foreign supplier verification programs.

Recent regulations implementing the Food Safety Modernization Act (FSMA) and the Food Supplier Verification Program (FSVP) will require significant expenditures by food producers for the U.S. market (both foreign and domestic) to ensure their production moves smoothly to market. FDA's 2015 rules governing Current Good Manufacturing Practices (CGMPs) are a leading example of the FDA's shift from post-production enforcement to a risk-based approach. Covered facilities must establish and implement a food safety system that includes an analysis of hazards and risk-based preventive controls. The use of this new hazards-based regulatory approach controlling production of food has increased compliance costs for most small-to-medium size food producers, including foreign exporters to the U.S.

In addition, FDA begins enforcement of the new FSVP rules for most food importers this month (small and very small importers will be exempt from enforcement for 6 months to a year). Under these new rules, importers are required to assess whether suppliers have adequately addressed the hazards inherent in growing and processing the food they provide. Importers must establish and follow written procedures to ensure that they import foods only from foreign suppliers approved based on an evaluation of the risk posed by the imported food and the supplier's performance. Importers not only have to assess their supplier's own risk assessment and preventive controls, they must document that assessment in case FDA requests that information. Should an importer fail to comply with the FSVP rules, their shipment will be subject to embargo (21 C.F.R. § 1.514(a)).

The CGMPs and FSVP are two areas in which President Trump could increase enforcement to disrupt incoming food flows and increase costs of exporting food to the U.S. Food producers of all sizes should be aware of the recent changes, which go to the heart of FDA's enforcement mission and which will occupy most of the agency's food-related enforcement efforts for the foreseeable future. FisherBroyles' federal regulatory team possesses significant expertise in this area and anyone with questions regarding the new administration's food trade policy, or the FDA's new food regulations should contact Chris Pey (646-233-2533) of FisherBroyles' New York office.

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